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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/068,528

Applicant(s)
Kolzumi et al.

Examiner
Manjunath N. Rao

Group Art Unit
1652



☒ Responsive to communication(s) filed on May 18, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-71 is/are pending in the application

Of the above, claim(s) 2-4, 6, 7, 9-14, and 21-71 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 5, 8, and 15-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Claims 1-71 are still at issue and are present for examination.

Election/Restriction

2. Applicant's election of Group I, claims 1, 5, 8 and 15-20 in Paper No. 14 is acknowledged. Applicant's election of species, orotic acid as nucleotide precursor, uridine diphosphogalactose as sugar nucleotide and galactose as sugar is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 2-4, 6-7, 9-14 and 21-71 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicants' arguments that "the claims to the nonelected process should be rejoined when a product claim is found allowable" for joining the groups I and II was unclear as both groups I and II are drawn to different process of making different products and neither one of them is a product group. Thus, claims of only Group I are now under examination. Further claims 5, 8, 15 and 17 will be examined only with reference to claim 1 which is an elected claim.

3. Examiner acknowledge's applicants letter, paper No. 15, dated 6-15-2000, regarding the clarification of the status of claim 19. Examiner regrets the inadvertent exclusion of claim 19 from the restriction. Claim 19 is now included in group I.

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Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the phrase "a treated product" in lines 6 and 8. It is not clear to the Examiner either from the specification or from the claims as to what Applicants means by "a treated product" and what is the "treatment" performed on what "product" of the culture broth.

7. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 17 recites the phrase "one kind of microorganism". It is unclear to the Examiner as to what applicants mean by "one kind of".

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for producing a single sugar nucleotide, uridine phosphogalactose, does not reasonably provide enablement for a process for producing any sugar nucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim 1 is so broad as to encompass a process for producing any sugar nucleotide. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of sugar nucleotides broadly encompassed by the claims. Since the production of each specific sugar nucleotide requires the use of specific enzyme with specific catalytic properties, predictability of which sugar nucleotide can be synthesized from the enzymes systems requires a knowledge of and guidance with regard to the specific enzymes needed, their production and reaction condition requirements and detailed knowledge of the methods to use the same. However, in this case the disclosure is limited to the enzyme systems required for the synthesis of a single sugar nucleotide, uridine phosphogalactose.

While enzyme isolation techniques and recombinant techniques are known, it is not routine in the art to screen multiple sources of enzymes or methods as encompassed by the instant claims, and the reasonable expectation of success in obtaining the desired enzyme are

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limited due to the complexity of the huge number of microorganisms, mammals, fungi and plants that need to be analyzed and the result of such isolation from an extremely large number of sources is unpredictable.

The specification does not support the broad scope of the claims which encompass the process of making all or any sugar nucleotide because the specification does **not** establish: (A) a rational and predictable method for making any sugar nucleotide; (B) the specification provides insufficient guidance as to which of the infinite possible choices of enzyme sources and methods is likely to be successful.

Thus, applicants have **not** provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a process to make any sugar nucleotide. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 8 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maruyama et al. (EP 0 553 821 B1, dated 3-19-1997) in view of Weissborn et al. (J. Bacteriol., 1994, Vol. 176:2611-2618). Claims 1, 5, 8 and 15-20 in this instant application are drawn to a method of producing a sugar nucleotide by allowing enzyme sources--a culture broth of microorganism capable of producing nucleotide-5'-triphosphate (NTP) from a nucleotide precursor and a culture broth of a microorganism capable of producing a sugar nucleotide from a sugar and a NTP--, the nucleotide precursor and the sugar to be present in an aqueous medium to form and accumulate the sugar nucleotide. Maruyama et al. teach a process of making a nucleotide-5-triphosphate such as uridine-5'-triphosphate (UTP) from a precursor such as orotic acid using the microorganism *Corynebacterium ammoniagenes* (see page 3). However, the reference does not teach the use of another microbial broth that has the capacity to transfer a sugar molecule to the NTP.

Weissborn et al. teach a microbial culture broth containing *E.coli* galU gene product, UTP:alpha-D-glucose 1-phosphate uridylyltransferase capable of producing a sugar nucleotide from a sugar and a NTP.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Maruyama et al. with that of Weissborn et al. to develop a method of making sugar nucleotide. One of ordinary skill in the art would be motivated to do this

as Betlach et al. Teach that the sugar nucleotides can be incorporated into industrially useful polysaccharide such as xanthan gum. One would have a reasonable expectation of success since Maruyama et al. provide the microbial broth for preparation of NTP from an inexpensive chemical such as orotic acid and Weissborn provide a culture broth with the enzyme required for the formation of the sugar nucleotide.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-

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3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Adrian Raut

16/00

Manjunath N. Rao

September 25, 2000